

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

HUMAN GENOME SCIENCES, INC.,)
Plaintiff,) C.A. NO. 08-166-SLR
v.)
GENENTECH, INC.,)
Defendant.)

**GENENTECH INC.'S OPENING BRIEF IN SUPPORT OF
ITS MOTION TO DISMISS**

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I. STATEMENT OF NATURE AND STAGE OF THE PROCEEDINGS

Plaintiff, Human Genome Sciences, Inc. (“HGS”), brings this lawsuit seeking District Court review of an interference before the Board of Patent Appeals and Interferences (the “Board”) of the United States Patent and Trademark Office (“PTO”) in Interference No. 105,361 (the “361 Interference”). There, HGS bypassed the PTO’s administrative procedures and unilaterally declined to participate in the Board’s hearing on the fundamental interference issue: whether HGS or defendant, Genentech, Inc., was the first to invent.

Plaintiff filed this action on March 25, 2008, invoking 35 U.S.C. § 146. (The same HGS patent is at issue in the co-pending *HGS v. Amgen* § 146 case, currently the subject of HGS’ motion for reconsideration after this Court dismissed that case for failure to exhaust administrative remedies. *Human Genome Sciences, Inc., v Amgen, Inc.*, No. 07-780-SLR, 2008 U.S. Dist. LEXIS 38464 (D. Del. May 9, 2008) (“Dismissal Opinion”.) Following stipulations to extend time, D.I. 5 & 7, this motion is Genentech’s first responsive pleading. Genentech requests dismissal of HGS’ complaint for failure to exhaust administrative remedies, because HGS leapfrogged the Board’s consideration of priority – which is also why the Court dismissed the co-pending *HGS/Amgen* case. In the alternative, and only if the Court concludes that this case should proceed despite HGS’ failure to exhaust, Genentech requests that certain claims be dismissed or stricken.

II. SUMMARY OF ARGUMENTS

The PTO is an administrative body and judicial review of its actions is subject to the Administrative Procedures Act (“APA”). Exhaustion of administrative remedies prior to judicial review is a fundamental requirement of APA law. The exhaustion doctrines grant deference to the delegation of authority to coordinate branches, and ensure that agencies, not the courts, have primary responsibility for the programs that Congress has charged agencies to administer. The

exhaustion requirements apply with special force in areas requiring an agency to apply its special expertise. The PTO has such special expertise. Moreover, when the statutory scheme requires administrative exhaustion in direct language, a District Court lacks subject matter jurisdiction. Here the statutory scheme states that the Board “shall” consider priority. HGS simply bypassed Board consideration of priority. A District Court has no jurisdiction to conduct an interference in the first instance. That, however, is what the complaint asks this Court to do. Whether this Court dismisses under Rule 12(b)(6) or 12(b)(1), this Court should dismiss this action.

Even if exhaustion did not bar HGS’ lawsuit, the Court should dismiss HGS’ assertions that the involved Genentech patent application claims are unpatentable for obviousness under 35 U.S.C. § 103. HGS did not raise § 103 in its intended motions list or in its motions. It cannot litigate such issues for the first time now. Even if exhaustion did not bar HGS’ lawsuit, the scope of the issues that this Court may choose to consider in this § 146 action is bounded by the issues that HGS properly raised and preserved below. HGS cannot now for the first time introduce § 103 issues in this action for judicial review under § 146.

The Court should also dismiss or strike HGS’ claims and prayer for sanctions. In the interference below, HGS complained about certain communications to the PTO by Genentech’s PTO counsel. Those communications occurred during prosecution of Genentech’s own patent application, which was not at issue in the ‘361 Interference, months before the PTO declared the interference. The Board dismissed HGS’ sanctions motion, concluding it should be addressed by the PTO’s Office of Enrollment and Discipline (“OED”). Approximately one year before HGS filed this lawsuit, the OED concluded that HGS’ complaint did not provide a basis for the OED to proceed. Although these allegations have no legitimate place in the litigation, they will have an illegitimate effect: to smear Genentech and its PTO counsel. That is improper.

III. FACTS

A. The Parties, and Interference Practice Generally

Genentech, one of the world's foremost biotechnology companies, specializes in discovering, developing and manufacturing recombinant protein-based therapeutics including treatments for cancer, rheumatoid arthritis, cystic fibrosis, heart attack, stroke, and age-related macular degeneration. Genentech is the assignee of U.S. Patent Application No. 10/423,448 (the “‘448 Application”), filed April 25, 2003, titled “Apo-2 Receptor Antibodies.” The ‘448 Application was at issue in the interference below.

HGS is the assignee of U.S. Patent No. 6,872,568 (the “‘568 Patent”), titled “Death Domain Containing Receptor 5 Antibodies, filed May 4, 2000. The ‘568 patent was at issue in the interference below and in the co-pending nominal § 146 action that this court dismissed.

Our patent law “recognizes the first to invent, rather than the first to file. Consequently, there exists a complicated administrative process by which the PTO has jurisdiction in the first instance to determine priority of invention.” *HGS v. Amgen*, 2008 U.S. Dist. LEXIS 38464 at *2. “The purpose of an interference proceeding is to resolve the question of priority of invention when more than one applicant seeks a patent on substantially the same invention.” *Scimed Life Sys. v. Medtronic Vascular, Inc.*, 468 F. Supp. 2d 60, 62 (D.D.C. 2006).

The Board has considerable agency expertise in the “highly specialized” technical and legal subject matters involved in an interference (*HGS v. Amgen*, 2008 U.S. Dist. LEXIS 38464 at *2), and was by statute exclusively granted the jurisdiction to conduct an interference to determine priority: “The Board of Patent Appeals and Interferences *shall* determine questions of priority of the inventions” 35 U.S.C. § 135(a).¹ By contrast, a district court does “not have

¹ All emphasis in quotes herein is supplied unless otherwise noted.

original jurisdiction to conduct an interference under § 1338(a) or any other statute because the PTO was granted that function exclusively in 35 U.S.C. § 135(a)." *Consolidated World Housewares Inc. v. Finkle*, 829 F.2d 261, 265 (Fed. Cir. 1987).

If a patent and, as relevant here, a patent application claim the same subject matter, the PTO declares an "interference," 37 C.F.R. § 41.203, identifying which party (the "Senior Party") is presumed to have "priority," and which party (the "Junior Party") must prove priority. 37 C.F.R. §§ 41.202, 41.203, and 41.207. An interference is generally divided into a "preliminary motions" phase and a "priority" phase. *HGS v. Amgen*, 2008 U.S. Dist. LEXIS 38464 at *2-3.

In the priority phase, the parties develop their proofs regarding who was the first to conceive of the invention(s) described in the count(s), the date(s) of reduction to practice, and diligence. The Board conducts a final hearing on those issues at which the parties present their proofs and argument. After that hearing, the Board issues a decision declaring which party has priority. 37 C.F.R. § 41.1 *et seq.* A party may request reconsideration. *Id.* § 41.127(d). A party dissatisfied with the Board's decision may appeal to either the Federal Circuit (under 35 U.S.C. § 141) or a district court (under 35 U.S.C. § 146).

B. The Interference Below

1. The Board Concluded Genentech Was Presumptively the First to Invent

On August 31, 2005, the PTO declared the '361 Interference between HGS' '568 Patent and Genentech's '448 Application. Declaration of Rebecca Fett ("Fett Decl.") Exh. 1. The Board designated the overlapping claimed subject matter as "Count 1" and "Count 2."

In the declaration notice, the Board accorded Genentech the benefit of certain Genentech patent applications, the earliest of which Genentech had filed May 14, 1998. The Board

accordingly identified Genentech as the “Senior Party” and HGS as the “Junior Party” with respect to both counts, thereby creating a rebuttable presumption that Genentech had invented the subject matter of the counts before HGS. *See* 37 C.F.R. § 41.207(a).

2. In the Motions Phase, HGS Did Not Request Permission to File a § 103 Motion

Consistent with the PTO’s interference rules, the Board issued a scheduling order providing that the ‘361 Interference would occur in two phases – the “Motions Phase” and the “Priority Phase.” During the Motions Phase, the Board required the parties to advise the Board of their intended motions, seek Board authorization to file such motions, and submit evidence and briefs in support of all authorized motions, which the Board would then decide. Pursuant to the Board’s rules and the Board’s Standing Order the parties were ordered to submit complete lists of all intended motions by October 20, 2005, including notice of relief sought and the basis for alleged entitlement to that relief. Fett Decl. Exh. 1 at 2; *id.* Exh. 13 at ¶ 26; 37 C.F.R. § 41.120(a). Board rules limited substantive motions to those consistent with the earlier notice. 37 C.F.R. § 41.120(b).

On October 20, 2005, HGS filed its intended motions list. Fett Decl. Exh. 2. As relevant here, HGS requested that the Board authorize it to file motions seeking to change the benefit accorded to HGS, “sanctions” against Genentech, and a motion for unpatentability of Genentech’s patent claims for anticipation under 35 U.S.C. § 102(e). Fett Decl. Exh. 2 at ¶ 12. HGS did not assert unpatentability on any other grounds, such as § 103.

The Board authorized certain of those motions. The Board did not authorize HGS to file its requested motion for unpatentability of Genentech’s claims for anticipation under § 102(e). Fett Decl. Exh. 3 at 3. HGS did not move for reconsideration of the Board’s rulings.

3. The Board Dismissed HGS' Putative Motion for Sanctions, and the OED Concluded No Disciplinary Action Was Warranted

As noted, HGS filed a motion putatively seeking sanctions against Genentech. The motion was not based on conduct alleged to have occurred during the '361 Interference. Instead, it was based on alleged misconduct of Genentech during *ex parte* prosecution of a Genentech patent application not involved in the '361 Interference or even in the same family as the Genentech '448 Application, approximately one year before the PTO declared the interference. HGS also filed a grievance with the OED based on the same Genentech PTO counsel's alleged misconduct.

After oral argument, the Board dismissed HGS' motion for sanctions, concluding: “[W]ithout deciding the truth of the allegations made by HGS, the matters alleged appear to be attorney conduct matters which do not impact the patentability of either HGS' involved patent or Genentech's involved application.” Fett Decl. Exh. 4 at 3. The Board decided that “the OED is better suited to addressing matters of potential attorney misconduct occurring during *ex parte* examination.” Fett Decl. Exh. 4.

The OED carefully considered HGS' allegations, and advised that HGS' grievance did not provide any basis on which to proceed. Fett Decl. Exh. 10 [FILED UNDER SEAL].

4. HGS Failed to Comply with the Applicable Legal Requirements in Seeking the Benefit of Earlier-Filed Applications

HGS moved for the benefit dates of six earlier-filed applications. To obtain the benefit of an earlier application, HGS had to prove that the earlier application would have shown one of ordinary skill at the time that HGS was in possession of the inventions described in the counts (*see Hyatt v. Boone*, 146 F.3d 1348, 1353 (1998)) and how to make and use the inventions of the counts without undue experimentation (*see Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997)). HGS failed to do so, which the Board confirmed.

On November 28, 2007, the Board denied HGS' motion. Fett Decl. Exh. 5. The Board emphasized that HGS failed to provide any argument whatsoever for four of the six applications and failed to provide a basis on which to grant the requested relief:

[T]here is no clear and direct comparison of the elements of Count 1 or Count 2 to the disclosures in any of the cited applications. This is the pivotal issue involved in any motion for benefit, so the absence of any direct comparison significantly disadvantages the movant. The panel will not make out the movant's case for it by rooting through reams of testimony for the elements of the count.

Id. at 14. The Board also rejected HGS' proffered expert testimony as "conclusory." *Id.*

5. HGS Unilaterally Refused to Proceed to the Priority Phase

Having concluded the Motions Phase with its November 28, 2007 decision, the Board set a schedule for the Priority Phase that required HGS to submit its priority papers by February 6, 2008. Fett Decl. Exh. 6. HGS, however, refused. Instead, it tried to bypass Board consideration of the priority issue specifically reserved to it by statute. *See* 35 U.S.C. § 135(a) (the Board "shall" consider priority). Instead of applying the rebuttable presumption of priority that resulted from the benefits decisions and trying to demonstrate priority and diligence, 37 C.F.R. § 41.207(a)(2), HGS filed a paper with the Board entitled "HGS's Intention to Not File a Priority Motion." Fett Decl. Exh. 7. In it, HGS unilaterally announced that it would bypass Board consideration of priority and instead file a District Court action under § 146.

Following HGS' refusal to file a priority motion, the Board entered final judgment on priority against HGS under 37 C.F.R. § 41.127(b), explaining: "The failure of a junior party to file a priority motion is construed as a concession of priority. Accordingly, it is appropriate to enter judgment." Fett Decl. Exh. 9 at 2. The Board awarded priority to the subject matter of Counts 1 and 2 to Genentech, and accordingly directed that the claims of HGS' '568 patent be cancelled. *Id.* HGS did not seek reconsideration, and never tried to put on a priority case before

the Board. Instead, HGS leapfrogged the Board and filed its nominal § 146 complaint in this Court.

IV. ARGUMENT: THIS COURT SHOULD DISMISS THIS CASE BECAUSE HGS FAILED TO EXHAUST THE ADMINISTRATIVE PTO PROCESS

“Federal courts are courts of limited jurisdiction. They possess only that power authorized by Constitution and statute.” *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). “[T]he burden of proving the existence of subject matter jurisdiction lies with the plaintiff.” *Carpet Group Intl. v. Oriental Rug Importers Ass’n, Inc.*, 227 F.3d 62, 69 (3d Cir. 2000); *accord, HGS v. Amgen*, 2008 U.S. Dist. LEXIS 38464 at *17. As explained below, this case must be dismissed, under Fed. R. Civ. P. Rule 12(b)(6) or 12(b)(1), because HGS failed to exhaust the administrative process in the PTO and specifically before the Board.

“It is a basic tenet of administrative law that a plaintiff must exhaust all required administrative remedies before bringing a claim for judicial relief.” *Robinson v. Dalton*, 107 F.3d 1018, 1020 (3d Cir. 1997).² There are two types of administrative exhaustion: prudential exhaustion (assessed under Rule 12(b)(6)), and jurisdictional exhaustion (assessed under Rule 12(b)(1)). We address them in that order. However, “[b]ecause there are no disputed facts as to what occurred in the interference, as opposed to the legal consequences that flow therefrom, the different standards of review applicable to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) are not material to the court’s determination of jurisdiction.” *HGS v. Amgen*, 2008 U.S. Dist. LEXIS 38464 at *17, n.4.

² The exhaustion doctrines under Federal Circuit and Third Circuit law are not meaningfully different.

A. Dismissal Is Appropriate Under Prudential Exhaustion

“[T]he [prudential] exhaustion doctrine is ‘grounded in deference to Congress’s delegation of authority to coordinate branches, that agencies, not the courts, ought to have primary responsibility for the programs that Congress has charged them to administer,’ and that the exhaustion requirement applies with special force when the agency proceedings in question ‘allow the agency to apply its special expertise.’” *Corus Staal BV v. United States*, 502 F.3d 1370, 1379-80 (Fed. Cir. 2007) (quoting *McCarthy v. Madigan*, 503 U.S. 140, 145 (1992)); accord *Republic Industries, Inc. v. Central Pennsylvania Teamsters Pension Fund*, 693 F.2d 290, 293 (3d Cir. 1982). The prudential exhaustion doctrine is a prerequisite to judicial review because it allows “the [administrative] tribunal to make findings of fact on which courts can later rely in their decision-making.” *Republic Industries*, 693 F.2d at 293; see also *Woodford v. Viet Mike NGO*, 548 U.S. 81, 88 (2007) (prudential exhaustion protects administrative agency autonomy).

“The [prudential] exhaustion requirement is properly imposed [to dismiss an action seeking judicial review] where, as here, the claim . . . *depends on careful factual analysis* and where the registrant has completely *sidestepped the administrative process* designed to marshal relevant facts and resolve factual issues in the first instance.” *McGee v. United States*, 402 U.S. 479, 488 (1971). That exhaustion requirement serves important policy goals by ensuring that litigants, administrative agencies, and reviewing courts obtain the benefits that flow when “the agency addresses the issues on the merits.” *Woodford*, 548 U.S. at 90. That exhaustion requirement, for the benefit of all concerned, “allows the administrative tribunal to exercise its own discretion, apply its own special expertise, and correct its own errors, thereby promoting administrative responsibility and efficiency *and minimizing the frequent and deliberate flouting*

of administrative processes which could weaken the tribunal's effectiveness." *Republic Industries*, 693 F.2d at 293.³

Those established concerns fit hand-in-glove with the facts and circumstances of this case. As this Court (and a widely-used treatise, Harmon's *Patents and the Federal Circuit*) has observed, the highly technical and complex priority issues that a Board is by statute charged with adjudicating in an interference have "been described as 'tortuous,' 'arcane,' 'highly specialized,' and 'virtually incomprehensible to the uninitiated.'" *HGS v. Amgen*, 2008 U.S. Dist. LEXIS 38464 at *2. In the '361 Interference, for example, the Counts were directed to "antibodies" that bind a specific cell surface receptor protein referred to as the "DR5 receptor." The DR5 receptor is a member of the TNF receptor (TNFR) "superfamily." An endogenous "ligand" for DR5 (also known as a "cognate ligand") is a protein termed Apo-2 ligand (also known as "TRAIL"). Count 1 in the '361 Interference was directed to "antagonist" antibodies and Count 2 was directed to "agonist" antibodies to the DR5 receptor. The terms "agonist" and "antagonist" refer to the biologic effects of these antibodies upon binding the DR5 receptor.

³ As this Court has explained, "[t]he purposes of the exhaustion requirement are to 'promote administrative efficiency, respect executive autonomy by allowing an agency the opportunity to correct its own errors, provide courts with the benefit of an agency's expertise, and serve judicial economy by having the administrative agency complete the factual review.'" *Patnande v. Gonzales*, 478 F.Supp.2d 643, 648 (D. Del. 2007) (Robinson, J.) (quoting *Robinson v. Dalton*, 107 F.3d 1018, 1020 (3d Cir. 1997)). In light of such considerations, in other administrative contexts this Court has dismissed actions seeking judicial review of agency determinations where, as here, there has been a failure to exhaust the administrative process before seeking judicial review. See, e.g., *Davis v. Social Security Admin.*, 2003 U.S. Dist. LEXIS 8744 (D. Del. May 20, 2003) (Robinson, J.) (dismissing action seeking judicial review of lack of subject matter jurisdiction where plaintiff failed to obtain final decision of agency (Social Security Administration) before bringing action); *Gant v. Nat'l Assn. of Securities Dealers, Inc.*, 791 F.Supp. 1077 (D. Del. 1992) (Robinson, J.) (dismissing action for judicial review based on plaintiff's failure to exhaust administrative remedies [NASD] and rejecting assertion that it would have been futile to pursue administrative remedies); see also *Patnande v. Gonzales*, 478 F.Supp.2d 643, 648 (D. Del. 2007) (Robinson, J.) (granting summary judgment to defendant in discrimination case for failure of plaintiff to exhaust administrative process).

Where prudential exhaustion applies, the plaintiff is permitted to assert that it would have been “futile” to continue the administrative process. *Corus*, 502 F.3d at 1379. The “narrow” futility exception may apply when the administrative process would have been “obviously useless.” *Id.* However, “[t]he mere fact that an adverse decision may have been likely does not excuse a party from a statutory or regulatory requirement that it exhaust administrative remedies.” *Id.*

The futility exception does not legitimize HGS’ attempt to avoid Board review here. Admittedly it is not likely that HGS would prevail. But the fact that HGS was not likely to prevail does not legally matter for exhaustion purposes. Indeed, when it identified its preliminary motions, HGS sought authorization to file a motion claiming that, based on its asserted earlier conception date and diligence, it could prove priority. Genentech had even invited an Order to Show Cause, explaining that if HGS thought it could prove diligence over a period of two years, and a prior conception, it should try. Fett Decl. Exh. 15.⁴ The Board did not grant Genentech’s request and proceeded to the Priority Phase, and HGS never sought to establish its case on priority despite its position that it would be possible for it to do so.

By sidestepping Board review of priority, HGS denied the Board, this Court, and the parties the benefits of the Board’s special technical and legal expertise. The Board never had the opportunity to engage in the “careful factual analysis,” *McGee*, 402 U.S. at 488, that the exhaustion requirement protects. The Board never had the opportunity to “make findings of fact on which [this] court[] c[ould] rely in [its] later decision-making,” *Republic Industries*, 693 F.2d

⁴ In its motion for reconsideration in the *Amgen/Immunex* lawsuit, HGS did not argue that trying to prove diligence over a three- year period would have been futile. Fett Decl. Exh. 18 at 7-8 (proving diligence would have been, “to be charitable, an extremely difficult endeavor.”).

at 293. And because of HGS' actions, the Board was not allowed to "apply its special expertise." *Corus Staal*, 502 F.3d at 1379-80.

Instead, HGS engaged in a "deliberate flouting of administrative processes," *Republic Industries*, 693 F.2d at 293, which – if allowed to stand – would encourage a Junior Party in an interference simply to leapfrog Board consideration of priority and file a § 146 action in District Court. *See Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 (Fed. Cir. 1994). This point bears emphasis: if HGS is correct – that an interference party can simply sidestep Board consideration of priority, once the Preliminary Motions have been decided, by filing a § 146 action in the District Court of that interference party's choosing – that would as a practical matter fundamentally alter and perhaps bring an end to the interference practice so carefully set forth in Title 35 of the United States Code and Title 37 of the Code of Federal Regulations. That outcome is fundamentally at odds with the policies underlying the requirement of exhaustion and interference practice as embodied in the Patent Act and the Patent Rules.

HGS has yet to cite any authority for the proposition that Congress intended to allow an interference litigant to cast aside that carefully crafted statutory and regulatory scheme. Indeed, in its motion for reconsideration in the co-pending *HGS/Amgen* § 146 action, HGS did not even acknowledge the administrative exhaustion doctrines that this Court applied in its Dismissal Opinion.

B. Dismissal is Appropriate Under Jurisdictional Exhaustion

As noted above, the exhaustion doctrine has two branches – "jurisdictional exhaustion" and "prudential exhaustion." *See Metropolitan Life Ins. v. Price*, 501 F.3d 271, 279 (3d Cir. 2007). Jurisdictional exhaustion applies when Congress requires resort to the administrative process as a predicate to judicial review – when the statute contains "sweeping and direct" language to that effect. *Weinberger v. Salfi*, 422 U.S. 749, 757 (1975). Jurisdictional exhaustion

is rooted, not in prudential principles, but in Congress' power to control the jurisdiction of the federal courts and to allocate responsibilities between the courts and administrative agencies. Whether a statutory framework requires exhaustion as a jurisdictional matter is a question of statutory interpretation, and where a statutory framework requires exhaustion, a court cannot excuse it. *Weinberger*, 422 U.S. at 757.

HGS has already argued to this Court that a “plain reading” of the statutory framework obligates the Board to complete the priority phase – not to have it bypassed by a party that has concluded that forum shopping is in its strategic self-interests. In Interference No 105,381, HGS explicitly argued that “[a] *plain reading* of 35 U.S.C. § 135(a) indicates that after an interference is declared, *the Board is obligated to determine the priority of invention*. . . . The Board is therefore *statutorily obligated* to continue with the priority phase.” Fett Decl. Exh. 14 at 2; *see also Human Genome Sciences, Inc., v Amgen, Inc.*, No 07-526-SLR-MPT, 2008 U.S. Dist. LEXIS 28153, at *19 (D. Del. Apr. 8, 2008) (Magistrate Judge Thynge’s Order, acknowledging HGS’ argument). In its motion for reconsideration in the *HGS/Amgen* case, HGS acknowledged neither its prior inconsistent argument nor this Court’s extensive analysis, some of which is quoted below in § IV(D), of jurisdictional exhaustion principles.

Here the statutory framework mandates exhaustion. It instructs that the Board “shall determine questions of priority.” 35 U.S.C. §§ 6, 135(a)). Not “may,” or “has the discretion to,” or – as HGS would re-write it – “may, unless a party elects to proceed directly to a District Court under § 146.” Only after the Board has complied with that statutory directive does the statutory framework allow an action in the District Court. The statutory framework provides no discretion, and where a statutory framework directs that an administrative agency “shall” perform an action, the requirement is mandatory, not discretionary. *See, e.g., National Ass’n of*

Home Builders v. Defenders of Wildlife, 127 S.Ct. 2518, 2531 (2007); *Merck & Co. v. Hi-Tech, Pharmacal Co., Inc.*, 482 F.3d 1317, 1322 (Fed. Cir. 2007).

The result that HGS now seeks cannot be harmonized with this law. It is true that the statutory framework does not contain a clause such as “an interference party shall not seek judicial review under § 146 until it has exhausted the Board’s administrative process.” But the statutory framework did not need to be that simplistic. It is established that under that statutory framework, a District Court does not have jurisdiction in the first instance to conduct an interference. *Consolidated World Housewares, supra*, 829 F.2d at 265. Accordingly, the statutory mandate that the Board “shall determine questions of priority” is most naturally and logically interpreted to mean that any such determination must be made by the Board in the first instance. This does not mean that a party is foreclosed from simply abandoning the interference, as HGS did below. It does mean, however, that if a party elects not to proceed with a Board determination of priority, that party cannot thereafter leapfrog the Board and seek judicial determination of priority in the first instance in the district court.

That logic and result is consistent with the fact that every Court that has discussed this issue – does § 146 contain an administrative exhaustion requirement? – has concluded that it does. We turn now to those cases.

C. Every Court that Has Discussed the Issue Has Concluded that § 146’s Statutory Scheme Contains An Administrative Exhaustion Requirement

Each of the four decisions that has discussed this issue has concluded that the statutory scheme underlying § 146 contains an administrative exhaustion requirement. A sister district court – affirmed by the Federal Circuit – so concluded in *Consolidated World Housewares, Inc. v. Finkle*, 662 F.Supp. 389, 390 (N.D. Ill. 1987) *aff’d*, 831 F.2d 261 (Fed. Cir. 1987): “the exhaustion of remedies before the PTO is normally a prerequisite to maintaining a civil action

[under § 146].” The D.C. Circuit, before the Federal Circuit’s creation, did, too. *General Motors v. R. E. Dietz*, 420 F.2d 1303, 1305-06 (D.C. Cir. 1969). The patent-experienced Eastern District of Virginia reached that same conclusion last year in *Enzo Therapeutics, Inc. v. Yeda Research and Devpt. Co.*, 477 F.Supp.2d 699, 710 (E.D. Va. 2007): “By first allowing the Board to make factual and legal findings [before an action under § 146], the court can take advantage of the Board’s specialized knowledge of the complex patent issues in dispute.” And, finally, this Court reached that same conclusion in dismissing the *HGS/Amgen* § 146 action based on HGS’ failure to exhaustion the administrative process.

Those conclusions are not surprising in light of the statutory language and the high degree of technical and administrative expertise that the Board brings to bear in determining questions of priority. The Federal Circuit has emphasized the “desirability of the expert agency [PTO] considering decisive matters relating to priority and patentability before they are raised in an action under § 146.” *Conservolite, supra*, 21 F.3d at 1103; see also *General Instrument Corp., Inc. v. Scientific-Atlanta, Inc.*, 995 F.2d 209, 211 (Fed. Cir. 1993) (an interference is an “administrative proceeding” before the PTO requiring administrative expertise).⁵

In short, like the Courts that discussed the issue before, this Court properly dismissed HGS’ § 146 action against *Amgen/Immunex*. We turn to that opinion as it applies to this lawsuit.

⁵ Cf. *DeSeveresky v Brenner* 424 F.2d 857, 859 (D.C. Cir. 1970) (Action for judicial review of PTO patentability determination under § 145; “the doctrine of exhaustion of administrative remedies [...] is applicable to actions brought to overturn determinations of the Patent Office ... [and] is a necessity of sound judicial administration, since the application of Patent Office expertise in the first instance may either obviate the need for judicial consideration, or illuminate the issues and facilitate the court’s disposition.”).

D. This Court Properly Dismissed HGS' § 146 Action Against Amgen/Immunex Based on HGS' Failure to Exhaust the Interference Process

This Court, well experienced with administrative exhaustion doctrines, *see* n.3, *supra*, properly applied the exhaustion requirements to dismiss HGS' § 146 action against Amgen/Immunex as a premature action for judicial review of an incomplete and non-exhausted interference record. In dismissing the case, this Court focused on "the scope of its ***jurisdiction*** in terms of ***exhaustion of administrative remedies.***" *HGS v. Amgen*, 2008 U.S. Dist. LEXIS 38464 at *20-21 (citing *Enzo*, 477 F.Supp.2d at 710).

This Court also explained in its Dismissal Opinion that in an action for judicial review of an interference proceeding, the public interest is best served "when a district court considering review of a decision of the Board resolves all issues of priority and patentability ***that have been raised and fully developed.***" *Id.* at *20 (quoting *Enzo*, 477 F.Supp.2d at 710). This Court examined its jurisdiction "in light of the facts of record," and concluded that the failure of HGS to exhaust the administrative interference process before the Board required dismissal of the action for judicial review, reasoning that HGS' actions amounted to effective usurpation of the Board's original jurisdiction:

[I]t is clear that the fundamental purpose of interference proceedings is to give the Board a full and fair opportunity to determine priority. It is evident from the record that HGS presented to the Board little more than conclusory arguments. Indeed, HGS failed to provide even enough information to allow the Board to specifically define the scope of the dispute. If the court were to allow HGS' 146 appeal to go forward on this record, it would constitute an **effective usurpation of the Board's original jurisdiction to determine priority.**

HGS v. Amgen, 2008 U.S. Dist. LEXIS 38464 at *23-24. This Court further explained that dismissal was appropriate in view of the potential for abuse where premature judicial review is sought and agency interference procedures are disregarded:

Moreover, HGS' failure to adequately develop the record leaves too much room for mischief in a 146 appeal, where supplemental discovery can be taken and new evidence proffered to the court. HGS may not have any administrative recourse if the appeal is dismissed, nevertheless, the court concludes that HGS has not carried its burden to prove that the court has subject matter jurisdiction under 35 U.S.C. 146.

Id. at *24. These determinations were proper and in accord with the extensive authority discussed above requiring exhaustion of the administrative process both as a matter of statutory construction and as a matter of development of the administrative record below before an action in district court to review the agency action. These determinations were particularly appropriate because HGS' decision to disregard the scheduled priority phase was a deliberate choice to "flout," *Republic Industries*, 693 F.2d at 293, the statutory requirement that the Board "shall" determine priority in an interference. 35 U.S.C. §§ 6, 135(a). Allowing a party such as HGS to leapfrog the agency process would pose precisely the debilitating effect on the agency, and would threaten agency independence by allowing litigants to sidestep agency decision-making on questions within the agency's unique expertise, that the case law cautions against. *Conservolite*, 21 F.3d at 1103. Absent an exhaustion requirement for § 146 actions, the PTO would be precluded from the opportunity to decide the issues it is supposed to decide. That result frustrates the statutory framework. *See id.* Because dismissal is warranted on these facts under either branch of the exhaustion doctrine – jurisdictional or prudential – this Court properly concluded that dismissal was appropriate under either Fed. R. Civ. P. 12(b)(1) for lack of jurisdiction or under 12(b)(6) for failure to state a claim under § 146.

V. ALTERNATIVE ARGUMENT: THIS COURT SHOULD DISMISS CERTAIN OF HGS' CLAIMS

A. HGS' § 103 Claims are Not Proper Here

1. Issues Not Properly Raised Before The Board are Precluded in an Action Under § 146

A § 146 action “is derivative of the interference conducted in the PTO.” *Rexam Inds. Corp. v. Eastman Kodak Co.*, 182 F.3d 1366, 1370 (Fed. Cir. 1999). Accordingly, “issues raised by the parties during the proceedings below or by the Board’s decision” determine the scope of an action under § 146, and thus “parties to an interference must make a complete presentation of the issues at the Board level so that the interference is efficient and not wasteful of administrative and judicial resources.” *Conservolite*, 21 F.3d at 1102. An issue is “deemed to have been raised for § 146 purposes if the record clearly demonstrates that it was placed before the examiner-in-chief *and* one or more parties *insisted* that the issue be resolved in the interference.” *Conservolite*, 21 F.3d at 1102. The PTO rules governing interference practice require that all issues to be decided by the Board be (a) listed on the motions list (or otherwise authorized by the Board) and (b) thereafter raised in the form of properly filed motions. *See* 37 C.F.R. §§ 41.120; 41.121; 41.208(a); Fett Decl. Exh. 13 ¶ 26.

Where an issue is not properly raised before the Board it cannot form the basis for a claim in an action under § 146. *Conservolite*, 21 F.3d at 1102. This is true even if the overarching issue was presented in the interference (which is not true here): under § 146 “[a] party may not, however, advance new legal theories at the trial court level, even if the overarching legal issue was presented below.” *Boston Scientific Scimed, Inc. v. Medtronic Vascular, Inc.*, 497 F.3d 1293, 1298 (Fed. Cir. 2007). “Failure to advance legal theories before the Board constitutes a failure to make a complete presentation of the issues, and permitting a

party to raise those theories for the first time before the trial court would be both inefficient and wasteful of administrative and judicial resources.” *Id.* (internal quotations omitted).

Issues are not adequately raised for the purpose of preserving them for § 146 review by a mere reference during the interference. In *General Instrument* the Federal Circuit affirmed the district court’s determination in a § 146 action to preclude a party from asserting an allegedly invalidating public use where the proponent of the evidence had failed to raise that issue of alleged unpatentability before the Board. The Federal Circuit explained: “In order for an issue to be raised adequately in an interference proceeding so that it qualifies for evidentiary review in a § 146 proceeding, more is required than passing reference to the subject during the course of the interference proceeding.” *General Instrument*, 995 F.2d at 214. Rather, “issues may only be deemed raised for § 146 purposes if the record clearly demonstrates that the issue was undeniably placed before the examiner-in-chief, and one or more parties insisted that the issue be resolved in the process of deciding which of the parties was entitled to priority.” *Id.*

Under this law, HGS’ § 103 claims are precluded under Fed. R. Civ. P. 12(b)(1) or Fed. R. Civ. P. 12(b)(6).

2. HGS’ § 103 Claims Are Precluded Here Because It Did Not Properly Raise § 103 (Or Even Raise It At All)

As required by the Board, HGS submitted its list of proposed motions in the ‘361 Interference on October 20, 2005. Fett Decl. Exh. 2. HGS sought permission from the Board to assert unpatentability solely based on anticipation under § 102(e). *Id.* at ¶ 12. The Board denied HGS’ request for authorization to file an unpatentability motion and HGS did not seek reconsideration of that decision. Other than anticipation under § 102(e), HGS’ proposed motion list did not include any other unpatentability motions and did not mention § 103. Indeed,

throughout the substantive motions phase of the ‘361 Interference, HGS never raised unpatentability under § 103.

After completion of the Motions Phase, in advising the Board that it did not intend to submit the required priority motion, HGS alleged that it had sought permission during a conference call to file a § 103 motion. See Fett Decl. Exh. 8 (referring to Paper 26, p.3). The cited Paper 26, however, did not refer to any § 103 argument. Accordingly, contrary to HGS’ assertion, HGS had not sought authorization of a § 103 motion during the motions phase. The Board so confirmed in its response to HGS’ February 4, 2008 filing:

During the interference, the parties sought authorization to file certain motions. Among others, HGS requested authorization to file a motion for unpatentability asserting that all of Genentech’s claims were *anticipated* under 35 U.S.C. § 102(e) over the disclosure of HGS’ involved patent. (Paper 23, p. 2, ¶ 12) That motion was not authorized. (Paper 26, p. 2). No request for reconsideration was filed . . . *HGS now seeks authorization to attack the patentability of Genentech’s claim on the same basis as previously requested in Paper 23.* In effect, *HGS seeks to revisit the earlier decision* declining to authorize the motion.

Fett Decl. Exh. 8 at 2.

The Board denied HGS’ effort to “revisit the earlier decision declining to authorize the motion,” stressing that the “fundamental purpose of an interference is to determine priority between two rival claimants of an invention,” and that a determination of patentability by the Board is not required. Fett Decl. Exh. 8 at 2. The Board further emphasized that the interference was at a “late stage,” that to grant HGS’ request “would substantially lengthen and increase the cost of this proceeding,” that HGS could file a protest under 37 CFR 1.291, and that “HGS’ reasons for reopening the motions period at this stage of the proceeding are insufficient.” Fett Decl. Exh. 8 at 3 (citing 37 C.F.R. §§ 41.1(b) and 41.200(c)). HGS did not seek reconsideration of the Board’s ruling, made no further mention of unpatentability under § 103, and did not file a protest under 37 CFR 1.291.

As the Board found, this conduct by HGS does not and cannot meet the requirement that the issue has been properly raised. The Board's determination not to authorize the filing of motions directed to unpatentability was within its discretion even in the first instance generally, *see, e.g., Sullivan v. Gately, 362 F.3d 1324, 1328 (Fed. Cir. 2004)* (Board did not abuse discretion in declining to address assertions of unpatentability, citing 35 U.S.C. § 135 that the Board "may" address patentability in any interference), let alone the facts and circumstances of this case.

Nor was HGS' attempt to shoehorn a § 103 issue into the interference by referring to it in a conference call after the close of the Motions Phase sufficient to raise the issue for purposes of preserving it for review under § 146. As the Federal Circuit made clear in *General Instrument*, more than a passing reference is required to preserve an issue for review under § 146; rather, the parties must properly raise the issues through preliminary motions or belated motions delayed for good cause. *General Instrument*, 955 F.2d at 214. Here, HGS did not raise the issue of obviousness in its preliminary motions and did not provide the Board with a good cause reason for allowing a belated motion. The sort of administrative leapfrogging based on a new litigation strategy that HGS now attempts is precisely the type of activity that is not permitted through the vehicle of an action under § 146. *Conservolite*, 21 F.3d at 1102 ("[a] proceeding under § 146 is not a chance for a party to reconstruct its case" from that presented to the Board in the PTO).

Further, the mere fact that HGS raised issues regarding unpatentability under one theory (anticipation) during the '361 Interference does not preserve its ability to raise new unpatentability theories in this § 146 action. As the district court in *Abbott* held, "the fact that priority, in general, was raised before the Board does not mean that Abbott may now choose to prove priority via a novel theory." *Abbott Labs. v. City of Hope*, 224 F. Supp. 2d 1200, 1202

(N.D. Ill. 2002). The court further concluded that “[b]y failing to properly raise the issue below, Abbott has indeed waived its opportunity to litigate the issue of Backman’s actual date of reduction to practice.” *Id.* And as the Federal Circuit thus recently held in *Boston Scientific Scimed, Inc. v. Medtronic Vascular, Inc.*, in an action under § 146 “[a] party may not, however, advance new legal theories at the trial court level, even if the overarching legal issue was presented below.” 497 F.3d 1293, 1298 (Fed. Cir. 2007). “Failure to advance legal theories before the Board constitutes a failure to make a complete presentation of the issues, and permitting a party to raise those theories for the first time before the trial court would be both inefficient and wasteful of administrative and judicial resources.” *Id.* (internal quotations omitted).

HGS’ claims for unpatentability under § 103 should accordingly be dismissed for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1), or, alternatively, for failure to state a claim under Fed. R. Civ. P. 12(b)(6).

B. The Court Should Dismiss HGS’ Sanctions Claims, Which Are Not Directed to Any Interference Issue and Which the PTO’s Discipline Office Rejected

HGS’ Complaint requests judgment that “the Board’s decision denying HGS’ request for sanctions against Genentech [be] reversed” (Complaint at ¶ (m)) and that “Genentech [be] sanctioned for interfering with the *ex parte* examination of HGS’ application which matured into the ‘568 patent.’” *Id.* at ¶ (n). These claims should be dismissed or stricken. They should not have been brought before the Board. And they have no legitimate place in this § 146 proceeding – although they do have an illegitimate collateral effect: to smear Genentech and its PTO counsel.

HGS’ sanctions motion before the Board below complained about certain alleged communications made by Genentech with the patent examiner during *ex parte* prosecution of a

Genentech patent application not at issue in the ‘361 Interference. That complaint made no sense then, and it has not improved with time. The complained-of communications could not have adversely impacted the HGS ‘568 Patent involved in the ‘361 Interference, as the ‘568 Patent in fact issued. Moreover, the challenged communications in the *ex parte* prosecution of the different patent application occurred *long before the ‘361 Interference was even declared.*

Notwithstanding those facts, HGS sought sanctions by the Board pursuant to Board Rule 128 (37 C.F.R. § 41.128) (*see* Fett Decl. Exh. 11 at 1). Rule 128, however, is limited to “Contested Cases” before the Board. *See* 37 C.F.R. 41.100-158 (Subpart D “Contested Cases”). This Rule thus could not have provided the Board with the authority to sanction Genentech because the alleged misconduct did not occur during a “contested case.” Rather, it occurred in an uncontested case (i.e., an *ex parte* prosecution) of a patent application that was not at issue in the Interference. HGS alleges no “misconduct” of the sort specified in Rule 128. The Board accordingly would have had no basis under Rule 128 to have sanctioned Genentech.

Indeed, during oral argument before the Board on HGS’ motion for sanctions, the Board questioned whether it even had jurisdiction to consider HGS’ allegations. *See* Fett Decl. Exh. 12 at 28:20-22 (“[W]hy do we have jurisdiction to sanction somebody for something that was done in a proceeding that was not before us?”). And in its ruling, the Board recognized that HGS’ allegations did not raise an interference issue: “[a]ssuming, without deciding, the truth of the allegations made by HGS, the matters alleged appear to be *attorney conduct matters which do not impact the patentability* of either HGS’ involved patent or Genentech’s involved application.” Fett Decl. Exh. 4. The Board thus concluded that the OED had been delegated the authority to investigate the type of conduct about which HGS complained:

We dismiss the [HGS] motion [for sanctions] since *OED is better suited to addressing matters of potential attorney misconduct*

occurring during ex parte examination. ... That Office has been delegated the authority to investigate and enforce the rules of conduct applicable to all those who represent applicants before the USPTO. ...

Fett Decl. Exh. 4. Accordingly, this Court, whose jurisdiction in this § 146 action is “derivative” of the Board’s (*see Rexam*, 182 F.3d at 1370), would be without jurisdiction to award sanctions as requested in HGS’ Complaint.

Moreover, the OED reviewed the matters that HGS raised, and it dismissed them. In a letter sent months before HGS filed the present § 146 action, the OED advised that HGS’ allegations provided no basis to proceed further and in particular that “no determination has been made that a violation of the U.S. Patent and Trademark Office’s (“USPTO”) disciplinary rules occurred.”⁶ Fett Decl. Exh. 10 [FILED UNDER SEAL]. The OED accordingly closed the case.⁷

The Court should be aware that, before bringing this issue to its attention, Genentech provided the redacted OED letter to HGS and asked that it withdraw the relevant allegations and prayer for relief. Fett Decl. Exh. 16 [FILED UNDER SEAL]. HGS refused. It failed to identify how the complained-of conduct was properly before the Board, failed to identify authority under which it would be properly before this Court, and failed to identify any authority for the relief that the complaint seeks. Instead, HGS made a veiled reference to somehow taking “discovery” on the issue, even though its allegations were based on written communications that HGS already has. Fett Decl. Exh. 17.

⁶ The identity of the Genentech patent attorney, who as noted above was exonerated, has been redacted in order to protect reputational interests.

⁷ The OED decision dismissing HGS’ grievance without initiation of disciplinary proceedings is final and not subject to administrative review. 37 C.F. R. §11.2(d) (“A decision [by OED] dismissing a complaint or closing an investigation is not subject to review by petition.”); *see also Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (“an agency’s decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency’s absolute discretion”).

In addition to Rules 12(b)(1) and 12(b)(6), Rule 12(f) provides a vehicle to remove this impertinent and scandalous issue from the litigation. Rule 12(f) authorizes the Court to strike from the pleadings “any redundant, immaterial, impertinent, or scandalous matter,” Fed. R. Civ. P. 12(f), that will not have bearing on the outcome of the litigation. *Bristol-Myers Squibb Company v. Ivax Corporation*, 77 F. Supp. 2d 606, 619 (D.N.J. 2000). While motions to strike “are not favored,” they should be granted where “the allegations have no possible relation to the controversy and may cause prejudice to one of the parties.” *Tonka Corp. v. Rose Art Industries, Inc.*, 836 F. Supp. 200, 217 (D.N.J. 1993).

That is precisely the case here. HGS’ claims seeking sanctions against Genentech are based on conduct that the Board has found to be irrelevant to the patentability of either HGS or Genentech’s involved claims and did not occur during the ‘361 Interference. Moreover, the OED determined that HGS’ claims of misconduct lack merit. Although these allegations have no legitimate place in the litigation, they will have an illegitimate effect: to smear Genentech and its PTO counsel. That is improper. Accordingly, whether subject to excisement under Rule 12(b)(1), 12(b)(6), or 12(f), HGS’ allegations and prayer have no place before this Court in this action.

VI. STATEMENT OF PRECISE RELIEF SOUGHT

For the foregoing reasons, Genentech respectfully asks that this Court dismiss this case in its entirety, under either Fed. R. Civ. P. 12(b)(1) or 12(b)(6), based on HGS’ failure to exhaust the administrative interference procedure below. In the alternative, and only if the Court does not dismiss the action, the Court should: (1) dismiss HGS’ allegations of unpatentability for obviousness under 35 U.S.C. § 103 issue (Complaint, Prayer ¶ (q)), for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1) or, if subject-matter jurisdiction is present, Fed. R. Civ. P. 12(b)(6) for failure to state a claim on which relief can be granted; and (2) dismiss HGS’

claims seeking or relating to sanctions (Complaint, Prayer ¶¶ (m), (n)) Fed. R. Civ. P. 12(b)(1) or, to the extent that subject-matter jurisdiction is present, stricken under Fed. R. Civ. P. 12(f).

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Dated: May 28, 2008
866759

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CERTIFICATE OF SERVICE

I, Philip A. Rovner, hereby certify that on May 28, 2008, the within document was filed with the Clerk of the Court using CM/ECF; that the document was served on the following party as indicated; and that the document is available for viewing and downloading from CM/ECF.

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